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ELI LILLY AND COMPANY

By

*KSRhoades*

Date

*4-23-02*

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants	:	Hoffmann, <i>et al.</i>	)	
			)	
Serial No.	:	09/744,431	)	
			)	Group Art Unit:
Filed	:	January 22, 2001	)	1647
			)	
For	:	FSH and FSH Variant Formulations,	)	Examiner
		Products and Methods	)	DeBerry, R.
			)	
Docket No.	:	X-12383M	)	

**RESPONSE TO RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents  
Arlington, VA 22202  
Sir:

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The Examiner has restricted the current application under 35 U.S.C. §§ 121 and 372 to the following groups:

Group I: Claims 92-106, 110-117, drawn in part to FSH or FSH variant, method of treating, process of preparing and article of manufacture.

Group II: Claims 118-131, 133-140, drawn in part to FSH or FSH variant wherein FSH or FSH variant comprises 90% FSH, method of treating, process of preparing and article of manufacture.

Group III: Claims 118-131, 133-140, drawn in part to FSH or FSH variant wherein FSH or FSH variant comprises dimers, method of treating, process of preparing and article of manufacture.

Group IV: Claims 92, 107-109, drawn in part to FSH or FSH variant.

Group V: Claims 118, 132, drawn in part to FSH or FSH variant dimers.

The Examiner asserts that the technical feature of Group I is FSH or FSH variant with preservative and that the technical feature of Group IV is FSH variant. The Examiner further requires that if Group IV or V is selected, the Applicants must elect one SEQ ID NO: for the  $\alpha$ -subunit and one SEQ ID NO: for the  $\beta$ -subunit.

The Applicants respectfully traverse the restriction requirement. "Claims may be restricted to a single disclosed embodiment (i.e., a single species, and thus be designated a *specific species claim*) or a claim may include two or more of the disclosed embodiments within the breadth and scope of definition (and thus, be designated a *generic or genus claim*). "*Species are always the specifically different embodiments.*" MPEP § 806.04(e) (emphasis in original). "Where there is no disclosure of relationship between species . . . , they are independent inventions and election of one invention following a requirement for restriction is mandatory." MPEP § 808.01(a). However, "[t]here must be a patentable difference between the species as claimed." *Id.*

Claim 92 of the instant application is a genus claim. It claims a formulation comprising a genus of proteins (FSH or FSH variants) and a preservative. Claim 107 claims a subgenus of FSH or FSH variants, all of which are within the genus of FSH or FSH variants. Claim 108 is a species claim which specifically claims human FSH. Claim 109 is another species claim; it claims an FSH variant. Both species are within the subgenus of Claim 107. More specifically, the species of Claim 108 is subsection (c) of Claim 107, and the species of Claim 109 is subsection (f) of Claim 107. Moreover, both species are within the genus of Claim 92.

**Claim 92: FSH or FSH variants + preservative(s)**

**Claim 107: Subgenus of FSH or FSH variants including:**

- bovine FSH
- horse FSH
- sheep FSH
- porcine FSH
- human FSH (Claim 108)
- human FSH variants (one is Claim 109)

Serial No. 09/744/431

The specification of the instant application provides "a disclosure of relationship between species." Page 10, line 24 begins a description of FSH and FSH variants described in the application. The disclosure describes the variants and incorporates references which further describe the variants and relationships between them. Page 13, line 10 begins a description of orthologous FSH species disclosed in the application, which include porcine, horse, bovine, sheep, and human FSH. One skilled in the art would understand the relationship between protein orthologs and variants. Finally, the relationship between species is visually displayed in the application on pages 13 and 14 through sequence listings of the various protein species.

In light of the preceding argument, the Applicants aver that there is no patentable difference between the species as claimed Groups I and IV. The Applicants respectfully request that the Examiner reconsider the restriction requirement between these two groups.

If the Examiner accepts the Applicants' request to combine Groups I and IV, the Applicants elect this combination group for examination. In particular, the Applicants elect the human species for examination; this species corresponds to SEQ ID NO:5 for the  $\alpha$ -subunit and SEQ ID NO:6 for the  $\beta$ -subunit.

However, if the Examiner does not accept the Applicants' request to combine Groups I and IV, the Applicants elect Group I for examination. No species election is required by the Examiner if Group I is elected.

The Applicants urge the Examiner to call the Applicants' agent at (317) 433-3422 if a telephone conversation would be helpful in expediting the prosecution of this case.

Respectfully submitted,

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